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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,407	02/07/2000	MICHAEL WILLIAM GRADY	JJM-399	6913

7590 02/14/2003

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,407

Applicant(s)

GRADY ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2002 has been entered.

2. The amendment filed February 11, 2002 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 1-12 and 14 have been amended.
- (E) Comments regarding Office Action have been provided drawn to
 - (a) Lack of unity of invention, which is maintained for the reasons of record;
 - (b) 103(a) rejection, which has been maintained for the reasons of record.

Claims 1-16 are pending in the case. Claim 16 has been withdrawn from consideration

The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Unity of Invention

3. Claim 16 has been withdrawn from consideration because of lack of unity of invention.

Applicant's arguments filed February 11, 2002 have been fully considered but they are not persuasive. Applicants argue that the burden for applicant for having to file, prosecute, and eventually maintained a second patent out-weighs the additional searching, that would be required to have Claim 16 examined with the currently pending claims. This argument is not persuasive. However, if the pharmaceutical composition of the instant application from which instant Claim 16 refers to is found allowable, then the subject matter of Claim 16 may be rejoined.

Claim Objections

4. Claims 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-10 are not clearly stated which renders the claims indefinite. There is no point of reference in the recited limitation of the dependent claims. That is, are the claims referring to the wound dressing or ointment or are the claims referring to the sulfated polysaccharide. For example, in Claim 2, the phrase - - wherein the sulfated polysaccharide - - should be inserted after "claim 1,"; in Claim 3, the term "which" should be changed to - - , wherein the sulfated polysaccharide; in Claim 8, the term "having" should be changed to - - , wherein the sulfated polysaccharide has - -. Each of Claims 2-10 should be reviewed for proper language and clarity.

In Claims 6 and 7, the term "saccharine residue" lacks clear antecedent basis, which renders the claims indefinite. It appears that the claims intended to refer to a "saccharide residue".

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. Claims 1-10 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Easton (EP 140,596) in view of Tunc (US Patent No. 3,939,836) for the reasons already of record on pages 4 and 5 of the Office Action mailed July 23, 2001.

Applicant's arguments filed February 11, 2002 have been fully considered but they are not persuasive. Applicants argue against this rejection on the grounds that the Easton reference contains no indication that the sulfated polysaccharides of the present invention are superior to other non-sulfated polysaccharides in binding MMP's as demonstrated by Applicants comparative data. This argument is not persuasive since Easton indicates a sulfated polysaccharide as an example of a polysaccharide that can be present in wound dressing thereof. See sulphate dextrans on page 4, line 34 of the Easton EP patent. The Tunc patent also suggests the presence of a sulfated polysaccharide, sulfated cellulose ester, which is well known as a component in wound dressings (see wound dressings in column 1, line 13 of the Tunc patent).

With regard to the limitation set forth in Claim 1 that the sulfated polysaccharide being present in an amount sufficient to bind matrix metalloproteinases, the fact that the sulfated polysaccharide is being used to bind matrix metalloproteinases is based on the intended use of the sulfated polysaccharide. However, a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F.2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161.

With regard to the claimed limitation for the amount of sulfated polysaccharide sufficient to bind matrix metalloproteinases, it is noted that the Easton EP patent and the Tunc patent do not discuss binding matrix metalloproteinases with the recited sulfated polysaccharide and the instant specification does not specify a particular value of what this amount would encompass. However, both references do indicate the presence of the sulfated polysaccharides in wound dressings. Applicants are reminded that the Office is in no position to determine experimentally whether or not, in an invention such as that at issue, the subject matter is the same as that of the reference. Accordingly, in such instances, this shifts the burden to the Applicants who have the resources to make such a determination and is in a better position to determine experimentally the differences between the invention as claimed and that of the art. *In re Pye*, 355 F.2d 641, 148 USPQ 426 (CCPA 1966).

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Accordingly, the rejection of Claims 1-10 and 13 under 35 U.S.C. 103(a) as being unpatentable over the Easton EP patent and the Tunc patent is maintained for the reasons of record.

7. Claims 1-10 and 13-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Spilburg et al (US Patent No. 5,679,375) for the reasons already of record on page 5 of the Office Action mailed July 23, 2001.

Applicant's arguments filed February 11, 2002 have been fully considered but they are not persuasive. Applicants argue against this rejection on the grounds that it is not obvious to use something for internal bodily treatment of gastric ulcers for topical wound dressing or ointment applications and method to bind MMP's present in chronic wounds. Applicants argue that gastric ulcers are quite different from chronic ulcers. See instant Claim 15 wherein the medical condition is only stated to be a chronic wound, which is a broad description of the medical condition that is claimed for treatment.

The arguments with regard to the claimed limitations directed to intended use and the amount of the sulfated polysaccharide sufficient to bind matrix metalloproteinases, which is address in the above arguments against the rejection of the claims under 35 U.S.C. 103, is incorporated into the current arguments for the rejection of Claims 1-10 and 13-15 under 35 U.S.C. 103 over the Spilburg et al patent. According-ly, the rejection of Claims 1-10 and 13-15 under 35 U.S.C. 103(a) as being unpatentable over the Spilburg et al patent is maintained.

Summary

8. Claims 1-10 and 13-15 are rejected; Claims 11 and 12 are objected to; and Claim 16 is withdrawn from consideration.

Examiner's Telephone Number, Fax Number, and Other Information

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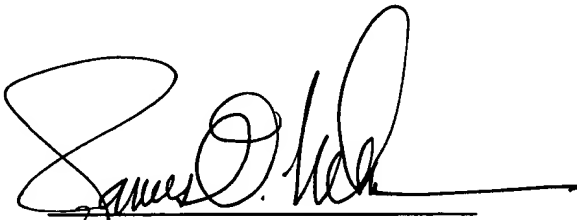
9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E. White


James O. Wilson
Supervisory Primary Examiner
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